

**NOT FOR PUBLICATION**

**UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY**

WARNER-LAMBERT COMPANY	:	
	:	
Plaintiff,	:	Civ. Action No. 99-922(DRD)
	:	
v.	:	
	:	
TEVA PHARMACEUTICALS USA, INC.	:	
	:	
Defendant.	:	
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SCHWARZ PHARMA, INC., SCHWARZ	:	Civ. Action No. 01-4995(DRD)
PHARMA AG and WARNER-LAMBERT	:	
COMPANY,	:	
	:	
Plaintiffs,	:	
	:	
v.	:	
	:	
TEVA PHARMACEUTICALS USA, INC.	:	
	:	
Defendant.	:	
	:	

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**Debevoise, Senior District Judge**

**I. Background**

The motions before the court arise in two related cases: i) Warner-Lambert Co. v. Teva

Pharm. USA, Inc., Civil Action 99-922 (the “Warner-Lambert Action”)<sup>1</sup> and ii) Schwarz Pharma, Inc., Schwarz Pharma AG and Warner-Lambert Company v. Teva Pharmaceuticals USA, Inc., Civil Action 01-4995 (the “Schwarz Pharma Action”). The court will assume familiarity with the underlying facts in these cases as set forth in the earlier opinions of this court and in the opinion of the Court of Appeals for the Federal Circuit in the Warner-Lambert Action.

In the Warner-Lambert Action this court issued a summary judgment on October 2, 2003 that claims 1, 4-10, and 12 of Warner-Lambert Company’s (“Warner-Lambert’s”) U.S. Patent No. 4,743,450 (“the ‘450 patent”) were not invalid by reason of obviousness and non-enablement and that Teva Pharmaceuticals USA, Inc., (“Teva”) infringes claims 1, 4-10 and 12 of the ‘450 patent. Warner-Lambert Co. v. Teva Pharm. USA, Inc., 289 F. Supp. 2d 515 (D.N.J. 2003).

After a bench trial this court held that the ‘450 patent is not unenforceable by reason of inequitable conduct and that claims 16 and 17 were not invalid by reason of anticipation or obviousness. The court entered final judgment, and Teva appealed to the Court of Appeals for the Federal Circuit.

On appeal Teva challenged the summary judgment of validity primarily on the ground that a genuine issue of fact remained as to whether the ‘450 patent was enabled. It contended that a person of ordinary skill in the art of pharmaceutical formulation would need to resort to undue experimentation in order to practice the invention. It supported its contention with a statement of its expert witness, Dr. Joseph B. Schwartz, that one of skill in the art would need to perform numerous experiments in order to practice the claimed invention. The Court of Appeals,

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<sup>1</sup> After the court disposed of summary judgment motions in the Warner-Lambert Action, the court granted the motion of Schwarz Pharma, Inc., and Schwarz Pharma AG (“Schwarz Pharma”), exclusive licensees of the ‘450 patent, to intervene.

after an extensive discussion of considerations determinative of the enablement issue and noting that this court had not in its opinion evaluated those considerations, stated “[n]ot knowing the reasoning of the district court, we have nevertheless considered the arguments of the parties, reviewed the limited record before us, and now conclude that Teva has presented fact-based arguments in support of its enabling defense that are deserving of consideration by the district court. . . Accordingly, we reverse the grant of summary judgment on Warner-Lambert’s motion for validity and remand to the district court for further proceedings on the issue of enablement.”

Warner-Lambert Co. v. Teva Pharm. USA, Inc., 418 F.3d 1326, 1338 (Fed. Cir. 2005)

With respect to infringement, Teva did not appeal summary judgment of infringement with respect to claims 16 and 17. With respect to claims 1, 4-10 and 12, Teva contended on appeal that Warner-Lambert did not present evidence showing i) that the quinapril in Teva’s formulation is susceptible to oxidative discoloration or ii) that any oxidative discoloration that does occur is inhibited by the magnesium carbonate. Warner-Lambert countered Teva’s position arguing, first, that the summary judgment should be affirmed because Teva did not timely disclose its discoloration defense and, secondly, because the evidence shows that in the absence of magnesium carbonate the quinapril in Teva’s product exhibits degeneration by oxidative discoloration.

The Court of Appeals held that, properly construed, “discoloration” means “oxidative discoloration” and “embodiments of claims 1, 4-10, and 12, must include an ACE inhibitor that is susceptible to oxidative discoloration, and must also include an alkali or alkaline earth metal carbonate (or bicarbonate) that inhibits oxidative discoloration.” 418 F.3d at 1340. The Court then held that “because Warner-Lambert made a prima facie showing that the quinapril in Teva’s

formulation was susceptible to oxidative discoloration, and because Teva failed to respond with specific evidence to the contrary, we hold that no reasonable juror could conclude that the quinapril in Teva's formulation was not susceptible to oxidative discoloration." Warner-Lambert, 418 F.3d at 1341-42.

The Court of Appeals, however, found inappropriate this court's grant of summary judgment of infringement to the extent that it found that the magnesium carbonate in the formulation inhibited discoloration. This court had relied on the fact that Teva had represented to the FDA that magnesium carbonate stabilizes its quinapril formulation, stating "[b]ecause lactose is claimed to inhibit hydrolysis, magnesium carbonate must be the inhibitor of the only two other kinds of degradation, cyclization and discoloration." Warner-Lambert, 289 F. Supp. 2d at 526. The Court of Appeals concluded differently, stating: "It is true that Warner-Lambert presented evidence showing that the lactose inhibits hydrolysis and that the magnesium carbonate inhibits cyclization. That does not necessarily mean, though, that the magnesium carbonate also inhibits oxidative discoloration. Accordingly, at this stage of the proceedings, drawing all reasonable inferences in favor of Teva, we must conclude that genuine issues of fact remain as to whether the magnesium carbonate in Teva's formulation inhibits oxidative discoloration of the quinapril." Warner-Lambert, 418 F.3d at 1342.

The Court of Appeals rejected Teva's contention that this court erred, when, after a bench trial, it found that Warner-Lambert had not engaged in inequitable conduct before the Patent Office, ruling "we cannot say that the court clearly erred in finding that Warner-Lambert inventors did not intend to deceive the PTO in not disclosing the existence of Vasotec®." Id., 418 F.3d at 1346.

Concluding that “there are genuine issues of material fact as to enablement and infringement of the ‘450 patent,” the Court of Appeals reversed this court’s grant of summary judgment on the issue of enablement with respect to claims 1, 4-10, 12, 16 and 17, and on the issue of infringement of claims 1, 4-10 and 12, the claims as to which Teva challenges the judgment of infringement. It remanded for further proceedings on those issues. Id., 418 F. 3d at 1348.

Related to the Warner-Lambert Action is the Schwarz Pharma Action in which Schwarz-Pharma, the manufacturer and distributor of the product in which the ACE inhibitor is moexipril, charges that Teva is infringing the ‘450 patent of which Schwarz Pharma is the exclusive licensee. On January 4, 2005 this court granted Schwarz Pharma’s motion for summary judgment that Teva’s moexipril hydrochloride tablets infringed claims 1, 6-8, 12 and 16 of the ‘450 patent. In particular the court found that the sodium bicarbonate in Teva’s moexipril formulation inhibited any oxidative discoloration of moexipril hydrochloride, as required by the ‘450 patent.

Also on January 4, 2005 this court granted Schwarz Pharma’s and Warner-Lambert’s motions to strike Teva’s affirmative defenses and counterclaims, including Teva’s First Separate Defense that the ‘450 patent was invalid and Teva’s First Counterclaim asserting invalidity. Teva’s invalidity defense and counterclaim were based in part on Teva’s assertion that the ‘450 patent is not enabled. The order striking Teva’s invalidity defense and counterclaim was based on collateral estoppel, the court having previously decided the issues in the Warner-Lambert Action to which, of course, Teva was a party.

A series of motions in the two related actions followed the Court of Appeals decision of

August 11, 2005.

## **II. The Motions**

Teva moved to vacate the January 4, 2005 order granting summary judgment of infringement to Schwarz Pharma. It noted that in the Schwarz Pharma Action this court found that there was no genuine issue of material fact as to whether the bicarbonate in Teva's moexipril product inhibits oxidative discoloration, reasoning, as it did in the Warner-Lambert Action, that the bicarbonate in Teva's moexipril product must inhibit both cyclization and oxidative discoloration because Teva's ANDA identifies the bicarbonate as a stabilizer. Because the Court of Appeals rejected this reasoning and held in the Warner-Lambert Action that the question whether the carbonate prevents discoloration raises issues of material fact, Teva argues that the same result must prevail in the Schwarz Pharma Action.

Teva also moved to vacate the January 2005 order striking Teva's defense and counterclaim of invalidity for lack of enablement. This court had stricken the defense and counterclaim because Teva had litigated the validity and enforceability of the '450 patent in the Warner-Lambert Action and under principles of issue preclusion could not relitigate those issues. Teva contends that the Court of Appeals decision reversing this court's enablement ruling and remanding the case renders application of the doctrine of issue preclusion inappropriate.

Warner-Lambert moved for an order granting summary judgment of infringement and enablement. As to infringement, it notes that the Court of Appeals left it open to this court on remand to determine whether to exercise its discretion to preclude Teva from advancing its carbonate-based discoloration defense. Warner-Lambert contended at the time of its summary judgment motions that this defense was raised too late. While sympathetic to that position the

court decided the issue (erroneously it now turns out) on the merits. Warner-Lambert raises the procedural issue once again.

As to enablement, Warner-Lambert notes that the Court of Appeals simply observed that this court had not addressed this issue, leaving the Court of Appeals without anything to review. Warner-Lambert contends that the remand does not preclude dealing with the enablement issue in a summary judgment context, and that the record before the court requires that summary judgment be granted in its favor.

Schwarz Pharma renews its motion for summary judgment of infringement, contending that, unlike the situation in the Warner-Lambert Action, Teva has established in its admissions as well as in its responses to Schwarz Pharma's contention interrogatories that the sodium bicarbonate in Teva's moexipril product prevents oxidative discoloration. Thus, Schwarz Pharma contends, it was entitled to the summary judgment of infringement contained in the January 4, 2005 order.

In the Schwarz Pharma Action i) Teva's motion to vacate this court's January 4, 2005 order granting Schwarz Pharma's motion for summary judgment of infringement against Teva as to claims 1, 6-8 and 12 of the '450 patent is granted, without affecting the grant of summary judgment of infringement as to claim 16; ii) a ruling on Teva's motion to vacate in part this court's January 4, 2005 order granting Schwarz Pharma's motion to strike Teva's First Affirmative Defense and Teva's First Counterclaim is deferred pending a trial on the issue of enablement in the Warner-Lambert Action; and iii) Schwarz Pharma's motion for summary judgment of infringement is denied.

In the Warner-Lambert Action i) Warner-Lambert's motion for an order granting

summary judgment of enablement is denied, and ii) Warner-Lambert's motion for an order granting summary judgment of infringement is granted.

### **III. Discussion**

A. Enablement: Warner-Lambert moves for summary judgment on the question of enablement, asking that the court do what it failed to do in its October 2, 2003 opinion, that is, review the evidence relating to this issue and confirm that there is no material issue of fact precluding summary judgment.

The Court of Appeals set forth the applicable law:

The enablement provision of the Patent Act requires that the patentee provide a written description of the invention "in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same." 35 U.S.C. § 112, ¶ 1 (2000). The purpose of this requirement is to ensure that "the public knowledge is enriched by the patent specification to a degree at least commensurate with the scope of the claims." Nat'l Recovery Techs., Inc. v. Magnetic Separation Sys., Inc., 166 F.3d 1190, 1195-96 (Fed. Cir. 1999); see also Donald S. Chisum, 3 Chisum on Patents § 7.01 (2002). Accordingly, we have held that the specification must provide sufficient teaching such that one skilled in the art could make and use the full scope of the invention without undue experimentation. CFMT, Inc. v. Yieldup Int'l Corp., 349 F.3d 1333, 1338 (Fed. Cir. 2003); Genentech, Inc. v. Novo Nordisk A/S, 108 F.3d 1361, 1365 (Fed. Cir. 1997); In re Wands, 858 F.2d 731, 736-37 (Fed. Cir. 1988). "The key word is 'undue,' not 'experimentation.'" Wands, 858 F.3d at 737 (citation omitted). That is, the specification need only teach those aspects of the invention that one skilled in the art could not figure out without undue experimentation. See, e.g., Nat'l Recovery Techs., 166 F.3d at 1196 ("The scope of enablement . . . is that which is disclosed in the specification plus the scope of what would be known to one of ordinary skill in the art without undue experimentation."); Wands, 858 F.3d at 736-37 (Enablement is not precluded by the necessity for some experimentation such as routine screening.").

418 F.3d at 1336-37.

Warner-Lambert starts with the presumption of validity of the patent, noting that the

burden of proving invalidity by clear and convincing evidence rests with the challenger. Atlas Powder Co. v. E.I. DuPont Nemours & Co., 750 F.2d 1569, 1573 (Fed. Cir. 1984). It contends that on the record before this court when the summary judgment motions were heard, Teva had produced no viable evidence to rebut that presumption.

All that was before the court was the statement of Dr. Schwartz, which Warner-Lambert contends should not be considered because it was not under oath. Even if it were considered, Warner-Lambert asserts that it had no probative value because Dr. Schwartz was incompetent to testify on the subject of enablement and, in any event, the fundamental premise underlying his opinion was wrong. He proceeded on the premise that pH plays a critical role in the stabilization of the potential ACE inhibitors, noting that the ‘450 patent does not mention pH and opining that “[w]ithout knowing that pH plays a role in the stabilization of quinapril, a person using the ‘450 patent would have to undergo undue experimentation to determine the appropriate amounts of ingredients (including the amount of stabilizer) needed to achieve a stable product.” (Dr. Schwartz’s Sept. 20, 2002 Certification, para 119). Because pH has no role in the stabilization of the patented composition, Warner-Lambert maintains that Dr. Schwartz’s certification has no probative value on the issue of enablement.

Warner-Lambert points to Dr. Schwartz’s deposition testimony that he has no evidence of anyone of ordinary skill in the art requiring undue experimentation to produce the patented product and notes that Teva was able to replicate the quinapril product after a limited period of experimentation.

Warner-Lambert addressed the new evidence that Teva submitted in opposition to Warner-Lambert’s motion in an effort to bolster its enablement defense. This evidence consisted

of a certification of Robert S. Coleman, Ph.D., who rendered an opinion that fosinopril is susceptible to both cyclization and hydrolysis and that reaction of fosinopril with magnesium carbonate in the presence of water will result in both cyclization and hydrolysis. The evidence also consisted of a certification of Gilbert S. Banker, Ph.D., D. Sc., who, in 51 pages, explicated the reasons for his opinion that, applying the factors enumerated in In re Wands, 858 F.2d 731, 736-37 (Fed. Cir. 1988), claims 1, 4-10, 12, 16 and 17 are not enabled. Warner-Lambert contends that the court should not accept this new evidence, to which it has not had an opportunity to respond and which has been submitted years after discovery ended.

Teva argues that the evidence in the record at the time the summary judgment was decided was sufficient to create a material issue of fact on the enablement issue. It notes the extraordinary breadth of the '450 patent's claims, purporting to cover the range of ACE inhibitors and their acid addition salts which are to be combined with an alkali or alkaline earth metal carbonate (of which there are eight) and saccharide (of which there are more than 100 and also derivatives of saccharides). Faced with the thousands of combinations of ACE inhibitors, carbonates and saccharides encompassed within the scope of the claims and the fact that only one working combination of ingredients is disclosed in the patent, Teva argues that the '450 patent provides virtually no guidance to pharmaceutical formulators in the full range of the claimed invention and is consequently not enabled.

It is Teva's contention that Dr. Schwartz's certification goes beyond his opinion regarding pH and contains sufficient additional opinions to create an issue of fact concerning enablement. Teva, of course, asks the court to consider the additional certifications that it has submitted.

The first question that must be addressed is whether Warner-Lambert's motion is permissible under the Court of Appeals ruling. The concluding paragraph of its opinion states, “[w]e hold that there are genuine issues of material fact as to enablement and infringement of the ‘450 patent. We therefore reverse the district court’s grant of summary judgment on the issue of enablement with respect to claims 1, 4-10, 12, 16 and 17, and on the issue of infringement of claims 1, 4-10 and 12, the claims with respect to which Teva challenges the judgment of infringement.” Warner-Lambert, 418 F.3d at 1348. (emphasis added).

In the body of the opinion the Court noted that the issue of enablement was difficult to review because this court had not addressed it in its opinion and stated “that Teva has presented fact-based arguments in support of its enablement defense that are deserving of consideration by the district court.” Noting Teva’s contention that at the time of filing for the ‘450 patent, one of skill in the art would have had to resort to undue experimentation in order to make the claimed formulations not disclosed in the patent’s two working examples, the Court of Appeals referred to Dr. Schwartz’s certification as support for this contention. Id., 418 F.3d at 1337. The Court did not state in this part of its opinion that Dr. Schwartz’s opinion created a material issue of fact on the enablement issue and simply stated it would “remand to the district court for further proceedings on the issue of enablement.” Id. 418 F.3d at 1338. Further proceedings could be renewal of the summary judgment motion or a trial of the issue.

It is unnecessary to determine whether the Court of Appeals limited the proceedings on remand to a trial of the issue, because further analysis of the Schwartz certification leads to the conclusion that despite its misconception of the role of pH, it contains enough additional material to create an issue of fact concerning enablement. It has now been sworn to, and therefore

Warner-Lambert's technical objection has been cured. His qualifications were sufficient to permit him to give an expert opinion.

The patent contains the full range of combinations that Teva notes. In addition to his mistaken opinion that lack of knowledge of the role of pH would require undue experimentation, Dr. Schwartz notes many other variables that would require undue experimentation. These would be present even if pH were not one of the variables (see Schwartz certification, para 124-130).

Thus there is an issue of material fact as to enablement of the '450 patent which will require a trial<sup>2</sup>. Warner-Lambert's motion for summary judgment regarding enablement will be denied.

B. Infringement: At the summary judgment stage Teva asserted as one of its non-infringement defenses the contention that magnesium carbonate did not inhibit degradation by discoloration in Teva's formulation. Warner-Lambert contended that this defense was untimely and that in any event it lacked merit. This court found that the lack of timeless argument had considerable merit and that "at the very least the circumstances required that Teva's motion for summary judgment be denied to give Warner-Lambert the opportunity to take discovery on the issue . . ." "Warner-Lambert, 289 F. Supp. 2d at 526. Nevertheless, the court decided the issue on the merits and granted summary judgment. Finding that the discoloration issue raised issues of material fact, the Court of Appeals reversed.

It stated, however:

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<sup>2</sup> Dr. Schwartz is ill and will not be able to testify. Another witness will have to be substituted in his place.

In reaching our conclusion, we offer no views as to Warner-Lambert's argument that Teva should be procedurally barred from asserting its discoloration defense. The district court seemed to agree with Warner-Lambert that the defense was untimely and prejudicial to Warner-Lambert. Nevertheless, the district court chose to dispose of the defense on its merits. Having reversed the district court's judgment on the merits, we leave to the sound discretion of the district court the matter of how to most appropriately proceed on remand.

Warner-Lambert, 418 F.3d at 1342.

This court is still of the opinion that the lack of timeliness argument has considerable merit, sufficient merit to have precluded Teva from advancing the discoloration defense so late in the proceedings.

When Teva filed this action in 1999 it admitted infringement. With Warner-Lambert's consent it amended its answer in the same year to assert non-infringement based on its contention that the lactose in its formulation did not inhibit hydrolysis. Discovery proceeded in reliance on the pleadings as thus framed. As the court stated in its 2003 summary judgment opinion:

Thereafter discovery proceeded for two years during which in contention interrogatories and otherwise Teva consistently maintained that the only claim limitation of the '450 patent that it did not meet was the claim limitation "a suitable amount of a saccharide to inhibit hydrolysis." Consequently, Warner-Lambert's deposition discovery, requests for admissions, interrogatories and infringement expert report concentrated on the non-infringement defense with respect to the lactose limitation. In particular Warner-Lambert's questioning of Teva's nine technical personnel concentrated on the lactose limitation and did not address the then uncontested carbonate claim limitation. Teva's contention interrogatories answers were not amended or supplemented to disclose any basis for the non-infringement contention other than the lactose limitation. Long after discovery was closed, and after Warner-Lambert submitted its infringement expert reports, Teva, through its expert, Dr. Gennaro, stated for the first time in its opposition expert report that Teva was asserting a non-infringement defense based on the carbonate limitation of the patent.

Warner-Lambert, 289 F. Supp. 2d at 525.

Teva argues that "Third Circuit case law requires that a party opposing the addition of a

new claim or defense ‘show that it was unfairly disadvantaged or deprived of the opportunity to present facts or evidence which it could have offered.’” (Teva’s Memo at p.4) (citing Bechtel v. Robinson, 886 F.2d 644, 652 (3d Cir. 1989)). However, the cases upon which Teva relies concerned motions to amend pleadings pursuant to Fed. R. Civ. P. 15(a). Motions to amend pleadings are freely given, absent prejudice to the non-moving party. For example Teva’s 1999 motion to amend its answer to add a non-infringement defense was not even opposed.

A totally different situation presents itself here. Teva, in response to contention interrogatories, limited its non-infringement defenses to the lactose defense. Extensive discovery proceeded exploring that defense. Discovery closed. Warner-Lambert submitted its infringement expert reports. Only in its response did Teva raise for the first time its discoloration non-infringement defense.

This was in total conflict with the schedule the court had established for discovery, summary judgment motions and, if necessary, trial of the case. Teva has advanced no justification for this delay and the delay could not help but cause at least some prejudice to Warner-Lambert, which, were the defense to be tried, would have to take additional discovery and assemble newly relevant evidence. Memories fade, documents are scattered, and marshaling the evidence in 2003 would not have been the same as marshaling it in 1999.

In these circumstances the appropriate course is to strike the discoloration infringement defense, cf., Fed. R. Civ. P. 37(c)(1).

C. Enablement Schwarz Pharma Action: On October 2, 2003 in the Warner-Lambert action the court granted Warner-Lambert summary judgment on Teva’s defense that claims 1, 4-10 and 12 of the ‘450 patent were invalid for obviousness and non-enablement. Thereafter

Schwarz Pharma intervened in the Warner-Lambert action. After a trial in that action held on May 3-6, 2004 on the remaining validity issues and on Teva's inequitable conduct defense, Teva's remaining defenses were rejected, and the '450 patent was found to be both valid and enforceable.

On September 17, 2004, Schwarz Pharma moved in the Schwarz-Pharma action for an order striking Teva's affirmative defenses and dismissing Teva's counterclaims alleging that the '450 patent is unenforceable and invalid. On January 4, 2005 the court ordered that Teva's First, Third and Fourth Affirmative Defenses be stricken and that Teva's Third Counterclaim seeking a declaratory judgment be limited by striking references to patent invalidity and unenforceability, because Teva had litigated the validity and enforceability of the '450 patent in the Warner-Lambert case, and under principles of issue preclusion Teva could not relitigate those issues.

Teva appealed the final judgment and summary judgment in the Warner-Lambert action. The Court of Appeals reversed this court's grant of summary judgment on the issue of enablement and infringement on the claims previously noted and for the reasons described above. Teva now moves for an order vacating this court's January 4, 2005 order striking Teva's First Affirmative Defense and Teva's First Counterclaim (as to patent invalidity) based on the application of the doctrine of issue preclusion and reinstating the defense and counterclaim of invalidity to the extent that they were based on lack of enablement.

The reversal in the Warner-Lambert action eliminates any support for the use of issue preclusion to strike Teva's defense and counterclaim based on invalidity for lack of enablement. Amalgamated Cotton Garment & Allied Indus. Fund v. J.B.C. Co. of Madeira, Inc., 608 F. Supp. 158, 163 (W.D. Pa. 1984). For the reasons set forth in Part III A of this opinion, there is to be a

trial in the Warner-Lambert Action on the issue of enablement. Teva will either benefit from, or be bound by, the results of that trial.

No purpose is served by vacating at this time the court's January 4, 2005 order striking Teva's defense and counterclaim to the extent that they were based on lack of enablement. If Warner-Lambert establishes enablement, the defense and counterclaim would have to be stricken once again. If Warner-Lambert fails to establish enablement an order can then be entered vacating the January 4, 2005 order striking the defense and counterclaim.

A ruling on Teva's motion will be deferred pending the trial of the enablement issue.

D. Infringement-Schwarz Pharma Action: On October 26, 2001, Schwarz Pharma filed its complaint alleging that Teva's moexipril product infringed the '450 patent, of which Schwarz Pharma is licensee.

On November 15, 2002 Teva moved for summary judgment of non-infringement. The court granted Teva's motion, adopting its claim construction from the Warner-Lambert Action that the sodium bicarbonate in Teva's formulation was not "an alkali or alkaline earth metal carbonate" within the meaning of the '450 patent. Thereafter Teva launched its generic moexipril product. The Court of Appeals for the Federal Circuit reversed, finding that "alkali or alkaline earth metal carbonate" means "both the carbonate and bicarbonate ions."

On August 2, 2004 Schwarz Pharma moved for a preliminary injunction ordering Teva to cease manufacture and sale of its moexipril product. After full briefing Teva agreed to withdraw its product from the market.

On October 1, 2004 Schwarz Pharma moved for summary judgment that Teva's moexipril product infringed claims 1, 6-8, 12 and 16 of the '450 patent. The court granted the

motion on January 4, 2005. On August 11, 2005 the Court of Appeals issued its opinion in the Warner-Lambert Action.

Teva moved for an order vacating the Court's January 4, 2005 order granting summary judgment of infringement to Schwarz Pharma as to claims 1, 6-8 and 12 (but not as to claim 16). Teva noted that in the Warner-Lambert Action the Court of Appeals rejected Warner-Lambert's contention that Teva's representation to the FDA that the carbonate functioned as a stabilizer established that the carbonate inhibits oxidative discoloration as well as cyclization. Teva further noted that in the Schwarz Pharma Action Schwarz Pharma relied on a similar argument to establish infringement, namely, that the bicarbonate in Teva's moexipril product must inhibit oxidative discoloration as well as cyclization because Teva's ANDA submitted to the FDA identified the bicarbonate as a stabilizer. It follows, Teva contends, that the reasoning of the Court of Appeals in the Warner-Lambert Action is equally applicable to the Schwarz Pharma Action and requires that summary judgment of infringement as to claims 1, 6-8 and 12 be vacated.

Schwarz Pharma opposes the motion and counters with a renewed motion for summary judgment that Teva has infringed claims 1, 6-8 and 12 of the '450 patent. It points out that there is no dispute that, as called for in claim 1: i) moexipril hydrochloride is susceptible to cyclization, hydrolysis and oxidative discoloration; ii) Teva's product contains an alkali or alkaline earth metal carbonate, sodium bicarbonate, and a saccharide, lactose monohydrate; iii) sodium bicarbonate stabilizes Teva's product against cyclization; and iv) lactose stabilizes Teva's product against hydrolysis. Addressing Teva's contention that Schwarz Pharma has not offered sufficient evidence that sodium bicarbonate is responsible for stabilizing Teva's product

against discoloration, Schwarz Pharma notes that both the product and the record are different in the Schwarz Pharma Action from the product and the record in the Warner-Lambert Action. Whereas in the latter action Warner-Lambert relied merely on the Teva submission to the FDA, in the former action Schwarz Pharma relies not only upon Teva's submission to the FDA, it relies on Teva's answers to requests to admit and interrogatories.

There can be no doubt that if the Court of Appeals decision undermines the basis of the infringement ruling in the Schwarz Pharma Action, the summary judgment of infringement should be vacated. “[A] judgment may be altered or amended if the party seeking reconsideration shows at least one of the following grounds: (1) an intervening change in the controlling law; (2) the availability of new evidence that was not available when the court granted the motion for summary judgment; or (3) the need to correct a clear error of law or fact to prevent manifest injustice.” Max’s Seafood Café, Inc. v. Quinteros, 176 F.3d 669, 677 (3d Cir. 1999).

In the present case grounds 1 and 2 are not available to Teva. There has been no intervening change in the controlling law and there is no new evidence available that was not available when the court granted the motion for summary judgment<sup>3</sup>.

Ground 3 is the only ground upon which the court can vacate the summary judgment of infringement in the Schwarz Pharma Action - the need to correct a clear error of law or fact to

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<sup>3</sup> In connection with the present motions Teva has submitted the results of tests performed by Dr. Eli Shefter. They purport to show that there is no observable discoloration even without sodium bicarbonate and, it follows, that the sodium bicarbonate in Teva's moexipril tablets does not function to inhibit any discoloration. The court is not taking into account this new evidence when deciding the motions and is relying on the record as it existed on January 4, 2005 when it issued its order granting summary judgment of infringement.

prevent manifest injustice. The Court of Appeals held that it was an error of law and fact to find that Teva's representation to the FDA that magnesium carbonate stabilizes its quinapril formulation requires a finding that magnesium carbonate necessarily stabilizes against discoloration. If the record in the Schwarz Pharma Action contains no more than Teva's representation to the FDA that sodium bicarbonate stabilizes its moexipril formulation it would be an error of law and fact to find that the sodium carbonate necessarily stabilizes against discoloration. Such an error of law should be corrected to prevent manifest injustice.

Schwarz Pharma contends that there were in the Schwarz Pharma action record several elements that were not contained in the Warner-Lambert Action record.

Teva's statement to the FDA in the moexipril application is in a somewhat different posture from its statement to the FDA in the quinapril application.

A reason for the Court of Appeals's rejection of the finding that magnesium carbonate inhibits oxidative discoloration was that "it may also be that some other excipient in the formulation is responsible." Warner-Lambert, 418 F.3d at 1342. In the Schwarz Pharma Action, however, that loophole was partially closed through the use of admissions that established the role of each other excipient, leaving sodium bicarbonate as the stabilizer against both cyclization and discoloration. Magnesium stearate is a lubricant. Crospovidone is a disintegrant. Pregelatinized starch is a disintegrant and a binder. Lactose is a filler (although subsequent proofs established that lactose stabilizes Teva's product against hydrolysis). This does not overcome the strong statement of the Court of Appeals that despite Teva's representation to the FDA, "Warner-Lambert, the party who bears the burden of proving infringement by a preponderance of the evidence, has not presented evidence to show that it is in fact the

magnesium carbonate that serves this particular stabilizing formulation.” Warner-Lambert, 418 F.3d 1342. An excipient, of course, can perform more than one function.

There was also included in the Schwarz Pharma Action summary judgment record Teva’s response to Schwarz Pharma Request for Admission No. 25.

Request for Admission No. 25 reads:

The sodium bicarbonate in Teva USA’s moexipril product provides that product with a degree of stability against discoloration sufficient to obtain regulatory approval of that product.

The response to the Request reads:

Teva USA admits that its ANDA #76-204 contains stability data which Teva believes will be sufficient to obtain regulatory approval for moexipril formulations having, at least, a two year shelf-life. Teva USA has informed the FDA that the sodium bicarbonate in its formulation acts as a stabilizer and the lactose in its formulation acts as a filler. As of the present time, however, the FDA has not specifically addressed the functional role or any excipient in Teva USA’s moexipril formulations and has not indicated whether regulatory approval of those formulations will be forthcoming. Accordingly, Teva USA is unable to admit or deny the request at the present time.

The first sentence, however, can be interpreted to admit that Teva’s formulation has achieved stability. The only element of instability that the Request addresses is discoloration and the response specifically states that “the sodium bicarbonate in its formulation acts as a stabilizer.” Nowhere in this response or elsewhere does Teva admit that any other excipient is a stabilizer against discoloration.

The next to the last sentence of the Response appears to be totally irrelevant to the Request, and the significance of the “Accordingly” introducing the last sentence is hard to fathom. Nevertheless the Response concludes with the forthright statement that “Teva USA is unable to admit or deny the request at the present time.” Schwarz Pharma did not press for

clarification of this convoluted total response, and it remained in effect until it was amended after summary judgment was rendered to deny that sodium bicarbonate provides moexipril with stability against discoloration.

Schwarz Pharma contends that Teva's response to Schwarz Pharma's interrogatories constitutes a further admission that sodium bicarbonate inhibits discoloration. In Interrogatory No. 1, Schwarz Pharma asked Teva to state and explain in detail each and every fact, basis or ground for its contention that its manufacture, use and sale of its moexipril product will not infringe the '450 patent. Teva's answer, served the same day as its Response to the Request for Admissions, asserted only two grounds for asserting non-infringement. The first was that the moexipril formulation does not contain an alkali or alkaline earth metal carbonate, a contention that the Court of Appeals claims construction ruling rejected. The only other non-infringement ground was that "the lactose in [Teva's] moexipril formulation does not act to inhibit hydrolysis, but merely acts as a filler." Teva did not contend as a further non-infringement ground that the sodium bicarbonate in its formulation inhibited discoloration. Schwarz Pharma urges that this omission, particularly in conjunction with Teva's response to Request for Admission No. 25, constitutes an additional admission further removing the Schwarz Pharma action from the ruling of the Court of Appeals on the subject of inhibiting discoloration.

The original contention interrogatory response adds nothing to Schwarz Pharma's case. When issued on January 6, 2003 Teva explicitly reserved the right to supplement its responses. In August 2004 Teva amended its contention interrogatory response to add that "plaintiffs have not established . . . that sodium bicarbonate inhibits discoloration in Teva USA's moexipril product." That was well before the summary judgment motion was decided and long before

discovery on the merits was over and before depositions or expert discovery.

In these circumstances the rationale of the Court of Appeals for reversing summary judgment of infringement in the Warner-Lambert Action is applicable in the Schwarz Pharma Action. Reliance on reasoning that the Court of Appeals held to be incorrect is an error of law which resulted in a finding of fact prematurely. The summary judgment order is subject to revision, Fed. R. Civ. P. 54(b), and the court has the discretion to vacate or modify the order at any time before final judgment has been entered. Inasmuch as material issues of fact exist with respect to the question whether sodium bicarbonate inhibits oxidative discoloration of Teva's formulation a trial is required.

For the above reasons Teva's motion to vacate the January 4, 2005 order summary judgment of infringement as to claims 1, 4-10 and 12 of the '450 patent will be granted. It follows that Schwarz Pharma's renewed motion for summary judgment of infringement on these claims will be denied.

### **III. Conclusion**

In the Warner-Lambert action the court will enter an order (i) denying Warner-Lambert's renewed motion for summary judgment regarding enablement and (ii) granting Warner-Lambert's renewed motion for summary judgment regarding infringement.

In the Schwarz Pharma action the court will enter an order (i) deferring a ruling on Teva's motion to vacate the January 4, 2005 order granting summary judgment to Schwarz Pharma as to enablement, pending a trial in the Warner-Lambert Action on the issue of enablement, (ii) granting Teva's motion to vacate the January 4, 2005 order granting summary judgment to Schwarz Pharma as to infringement of claims 1, 6-8, and 12 of the '450 patent, and (iii) denying

Schwarz Pharma's renewed motion for summary judgment of infringement of claims 1, 6-8, and 12 of the '450 patent.

Dated: January 31, 2006

/s/ Dickinson R. Debevoise  
DICKINSON R. DEBEVOISE  
U.S.S.D.J.